



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville MD 20857

JUN 20 2002

Carl D. D'Ruiz, M.P.H.
Director, Product Stewardship & Regulatory Affairs
Ciba Specialty Chemicals
Consumer Care & Colors
4090 Premier Drive
P.O. Box 2444
High Point, North Carolina 27261-2444

RE: Docket No. 96N-0277

Dear Mr. D'Ruiz:

In the FEDERAL REGISTER of January 23, 2002 (67 FR 3060), the agency published a final rule entitled "Additional criteria and procedures for classifying over-the-counter (OTC) drugs as generally recognized as safe and effective and not misbranded." In that rule, the agency said it would give priority review to any party converting an old citizen petition (CP) (for considering certain foreign conditions for OTC drug monographs) to the new Time and Extent Application (TEA) format if the TEA was submitted within 120 days after publication of the final rule (i.e., by May 23, 2002). Subsequently, the agency notified you by letter dated April 19, 2002 that it did not intend to take further action on your CP and to submit a TEA in the required format if you wished to pursue inclusion in the OTC drug monograph system of an OTC drug product or active ingredient that was the subject of the CP.

It has come to our attention that, in some cases, the age of the original petition and the location of the petitioner (i.e., outside the United States) have made it difficult to obtain information required for a TEA and thus complicated its preparation. In addition, we realize that the agency's letter notifying petitioners about converting their petitions to TEAs was not sent out until the end of April 2002.

For these reasons, we believe that a 90-day extension of the May 23, 2002 date is appropriate. Therefore, if the above referenced TEA is submitted by August 21, 2002, it will be given priority review.

If you have any questions, please contact Walter Ellenberg, Ph.D., Regulatory Health Project Manager, at 301-827-2222.

Sincerely yours,

Charles J. Ganley, MD

Director

Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

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